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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,050	02/20/2002	David W. Osborne	359872001400	2420

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/081,050	Applicant(s) OSBORNE, DAVID W.	
	Examiner Lakshmi S Channavajjala	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: |

Art Unit: 1615

DETAILED ACTION

Receipt of Declaration and IDS dated 6-5-02 is acknowledged.

Claims 1-26 are pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 13, 14, 20, 21 and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,060,085 or US 5,863,560, both patented to Osborne ('085 and '560).

'085 and '560 discloses topical therapeutic compositions for the treatment of acne. The composition is in the form of semi-solid aqueous gel, where in the pharmaceutical is dissolved and in microparticulate form (col. 2, summary of invention- both '085 and '560). Particularly, Osborne discloses that the composition is effective with dapsone as an active agent (col. 3 of '085 and '560). Examples 2-6 in col. 9-11 (both the references) recite compositions containing dapsone, with other cosmetic additives such as methylparaben, which reads on claimed preservative. Table 1 (col. 13, both patents) recite 3% dapsone concentration. Both references teach dapsone in a topical composition and for the same purpose i.e., treatment of acne. Accordingly, the ability to treat inflammatory and non-inflammatory acne is inherent to the composition of both the references. Osborne also discloses the method of preparing the dapsone composition involving the claimed steps (col. 7, lines 10-25 of both patents). With respect to the method of preventing non-inflammatory acne lesion from becoming inflammatory acne, the

Art Unit: 1615

dissolved portion of dapsone in the composition of Osborne passes through stratum corneum in to lower third of pilosebaceous unit, whereas the microparticulate dapsone crosses stratum corneum only minimally. Thus, once the herpes lesion vesicle ruptures and the stratum corneum is no longer in place, then the microparticulate dapsone is only dissolved and is released for sustained and significant therapeutic benefit, thus preventing the development of inflammatory lesion (col. 2). Therefore, Osborne ('085 and '560) anticipates the instant claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,200,964 to Singleton et al ('964) in view of Osborne ('085 or '560).

'964 teach acne treatment composition comprising salicylic acid as an active agent for the treatment and prevention of acne (col. 1). '964 teach addition of active agents such as sunscreens, antioxidants, fragrances etc., (col. 4) and teach the composition in the form of spray, cream, lotion, suspension, gel etc (col. 7, lines 20-31). '964 further teach addition of dermatologically active agent such as dapsone in the composition. However, '964 fail to explicitly teach dapsone for treating acne.

The teachings of Osborne ('085 and '560) have been discussed above. It would have been obvious to one of an ordinary skill in the art at the time of the instant invention to use dapsone in the composition of '964 as an additional anti-acne agent because Osborne teaches dapsone as an

Art Unit: 1615

effective anti-acne agent and using dapsone in an dissolved and a microparticulate forms in the same composition enables immediate treatment of inflammation as well as prevention of inflammatory lesions. Further, preparing the dapsone containing composition in the different formulations such as a cream, lotion, gel without losing the anti-acne activity would have been within the scope of a skilled artisan.

Claim Rejections - 35 USC § 112

Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claims recite a method of treating acne or a method of preventing a non-inflammatory acne lesion from becoming an inflammatory lesion by topically applying a dermatological composition. However, the claim is indefinite because it is vague and unclear from the claims if the composition is applied to even normal skin or to applied to acne lesion and/or non-inflammatory acne lesion. It is suggested to applicants that the claims recite the limitations such as "said acne" or "said non-inflammatory acne lesion".

Claim 24 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating acne, does not reasonably provide enablement for prevention of non-inflammatory lesion from becoming inflammatory lesion. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: nature of the invention, breadth of the claims,

Art Unit: 1615

state of the art, guidance of the specification, predictability of the art, and the working examples.

All the factors have been considered with regard to the claim, with the most relevant factors discussed below.

Instant claim is drawn to a method of prevention of non-inflammatory lesion from becoming inflammatory lesion. Throughout the instant specification applicants teach a method of treating acne. Further, applicants state (page 4 of specification) that the term "treatment refers to reduction in number and/or severity of individual acne lesions, prevention or global improvement in appearance of acne lesions. Thus, applicants equate prevention of inflammatory lesions with treatment of acne but fail to describe any method of preventing the development of inflammatory lesion. Acne is known to be caused by complex interaction of bacteria and androgens resulting in enlargement of sebaceous glands, growth of anaerobic bacteria and finally in the constriction of follicles and ducts. Such closed comedones are non-inflammatory and applicants have shown results in treating acne lesions with dapsone containing formulation. While applicants state that the closed comedones are potential sites for inflammatory lesions, applicants do not teach if all the potentially inflammatory comedones turn or result into inflammatory lesions. Further, applicants do not provide any guidance as to the length or duration of administration of dapsone such that the development of inflammatory lesion is possible. Furthermore, there is no guidance or teaching as to a complete prevention is possible by administering or applying dapsone, or regarding the amount of dapsone required for complete prevention. In the absence of any teaching or guidance, one of an ordinary skill in the art would have to trial and error experimentation to use compositions containing dapsone for preventing

Art Unit: 1615

non-inflammatory acne lesions to inflammatory lesions. For examination purposes, the phrase "controlling or preventing" is interpreted as "treating".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lakshmi S Channavajjala
Examiner
Art Unit 1615

July 7, 2003